Journal of
Clinical Research and Drug Development

Volume 1, Number 1, April 1987

Contents

EDITORIALS

Comments from the Editor
Allen Cato
1

Editorial Board
3

The ACP Welcomes the *Journal of Clinical Research and Drug Development*
Mary Jane Baine and Linda Cook
9

REVIEW ARTICLE

Genetic Toxicology: From Theory to Practice
D. Clive
11

Commentaries by Paul M. Newberne, John Ashby, M. Schach von Wittenau, and Motoi Ishidate
42

ORIGINAL ARTICLES

Adverse Drug Events: Global Collection, Analysis, and Reporting
Max W. Talbott, Pamela A. Hadley, Winston C. Lister, Maribeth Rader, Robert E. Hizer, Cornelius W. Pettinga, and W. Leigh Thompson
53

Clinical Trials Are Not Enough: Drug Development and Pharmacoepidemiology
Gerald A. Faich, David H. Lawson, Hugh H. Tilson, and Alexander Walker
75

CASE REPORT

The Case of the Disappearing White Blood Cells
Anthony T. Dren, Charles W. Gorodetzky, and Allen Cato
79

Discussion by James Niedel

THE LIGHTER SIDE

Have You Noticed That There Aren't Many Old Monitors Around?
David M. Cocchetto
87

ANNOUNCEMENTS

Program of the Annual ACP Meeting
91

Meetings of Interest
94

Journal of
Clinical Research and Drug Development

Volume 1, Number 2, June 1987

Contents

ORIGINAL ARTICLES

Routine Laboratory Tests in Clinical Trials: Interpretation of Results
W. Leigh Thompson, Rocco L. Brunelle, Gregory G. Enas, and Patrick J. Simpson
95

Current Phase I/II Designs: Are They Adequate?
Barry Storer and David DeMets
121

Federal Protections for Human Research Subjects: Historical Perspective
Charles R. McCarthy
131

Review of Investigational Biological Products by the United States Food and Drug Administration
D. Bruce Burlington and Edward R. Gubish
143

Achievement of Continuity and Research Equity in Clinical Drug Development
Ronald V. Nardi and David M. Cocchetto
153

Centralization Versus Decentralization Management Specific to Clinical Research Associates in the Pharmaceutical Industry
Mary Jane Baine
167

Commentary on "Genetic Toxicology: From Theory to Practice," by D. Clive
J. Clin. Res. Drug Dev. 1:11–41 (1987)
Francis C. R. Roe, W. Gary Flamm (with Sidney Green), Vera Glocklin, and Stephan Madle (with Lutz Müller and Rolf Bass)
179

BOOK REVIEW

Human Experimentation: A Guided Step into the Unknown, by William A. Silverman
David M. Cocchetto
185

Journal of
Clinical Research and Drug Development

Volume 1, Number 3, September 1987

Contents

ORIGINAL ARTICLES

Accuracy of Data Collection in a Clinical Trial with Guidelines for Case Report Auditing
David M. Cocchetto, James R. Johnson, and Karen Werner
187

A Postmarketing Evaluation of Levobunolol, a Topical Antiglaucoma Drug
Gary D. Novak, Cheryl Y. Eto, John C. Lue, and Mary-Jane Branin
197

Survey of Concurrent Diseases and Pharmacotherapeutics in Impotent Elderly Men
David D. Michie, Geneva L. Schwaig, and Lawrence V. Schoenfeld
205

IN MEMORIAM

In Memoriam: Patricia Holly Russell, M.D.
217

THE LIGHTER SIDE

Moving On and On
Paul E. Stang
221

LETTER TO THE EDITOR
223

ANNOUNCEMENT

Associates of Clinical Pharmacology Membership
225

ABSTRACTS

Eleventh Annual Meeting of the Associates of Clinical Pharmacology
227

Third Annual Conference on Pharmacoepidemiology
237

Journal of
Clinical Research and Drug Development

Volume 1, Number 4, December 1987

Contents

ORIGINAL ARTICLES

Implementation of the Drug Price Competition and Patent Term Restoration Act of 1984: A Progress Report
Kenneth I. Kaitin and A. Gene Trimble
263

The Bendectin Saga: "Voluntary" Discontinuation
C. I. Barash and L . Lasagna
277

Prolonged Normotension After Abrupt Withdrawal of Terazosin Treatment: Implications for Studies of the Efficacy of Antihypertensive Drugs
Gary E. Ruoff
293

Commentary on "Prolonged Normotension After Abrupt Withdrawal of Terazosin Treatment: Implications for Studies of the Efficacy of Antihypertensive Drugs," by Dr. Gary E. Ruoff
Ronald V. Nardi
301

Serum Concentrations and Adverse Effects of Vancomycin in Pediatric Patients
M. C. Nahata and J. W. Kammer
307

THE LIGHTER SIDE

The Monitor's Briefcase
David M. Cocchetto
313

BOOK REVIEWS

Guide to Clinical Interpretation of Data, by Bert Spilker.
Peter H. Vlasses
315

Who Goes First? The Story of Self-experimentation in Medicine? by Lawrence K. Altman
Peggy Hull
317

ACKNOWLEDGMENTS
319

AUTHOR INDEX TO VOLUME 1
321

SUBJECT INDEX TO VOLUME 1
323

TABLES OF CONTENTS FOR VOLUME 1